

JUN. 4. 2002 11:38AM

FOLEY LARDNER

NO. 3873 P. 1/3

#8

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FACSIMILE TRANSMISSION

Total # of Pages **3** (including this page)

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From :	Jay P. Hendrickson
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Date :	June 4, 2002
Client/Matter No :	034621-0102
User ID No :	3373

MESSAGE:

Mr. Chakrabarti,

I attach a copy of the Declaration of Gin Wu, Ph.D. which was previously submitted with our Response to the Office Action dated May 17, 2002 in connection with Appl. No. 09/764,783.

Very truly yours,

Susan J. Jaber

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DECLARATION OF GIN WU, Ph.D.

I Gin Wu, declare that:

1. I am a joint inventor with Gloria Elena Leon Paz De Rodriguez of the subject matter which is claimed and for which a patent is sought on the invention entitled: **METHOD OF PROCESSING BLOOD SAMPLES IN ORDER TO PRODUCE DNA COMPLEX PATTERNS FOR DIAGNOSTIC APPLICATIONS**, which was filed on 01/17/2001, as United States Application No. 09/764,783.

2. I hereby declare that the subject matter set forth in the Response to Office Action and Amended Claims was part of our invention and was invented before the filing date of the above-identified original application for such invention.

3. The inventors used the method of the present invention to produce DNA complex patterns of approximately 300 healthy women and 300 healthy men, and the results are described in the specification at page 11, lines 5-14; and shown in Figure 4, which is representative of the results from all patterns that were produced.

4. The inventors also used the method of the present invention to produce DNA complex patterns of approximately 1,000 pregnant women, and the results are described in the specification at pages 9, line 3 through page 11, line 4 and shown in Figures 2A through 3E, which are representative of the results from all patterns that were produced.

5. The inventors also used the method of the present invention to produce DNA complex patterns of approximately 50 women with breast cancer and 20 women with cervical cancer. These results are set forth at page 11, line 14 through 22, and in Figures 5 and 6, which are representative of the results from all patterns that were produced.

6. Applicants' experiments with pregnant women and nonpregnant women also revealed that the DNA complex patterns for any given blood sample from the same person exhibited practically identical shapes.

7. The phenol used in the method of the present invention does not strip off all of the nucleoprotein complex phenol by itself cannot strip off all of the complex. In order to do so, the tissue must initially be treated with protease (e.g., a histone or histone protein). The present invention does not include this step.

8. The examiner states that the DNA structure would be expected to change depending on the phase and development of white blood cells and implies that the present inventor does not disclose a method of quantifying the change. But the present invention is not directed to identifying the transient changes to the DNA structure related to cell growth. Rather, the present invention relies, in part, upon the fact that the DNA structure changes as part of a rearrangement process which takes place in bone marrow and which has been shown to be critical to the production of a vast variety of white blood cells with each variety containing a uniquely rearranged DNA structure. What is significant to the present invention is that after the mature white blood cells enter the blood stream, some of the cells produce specific clones as part of an immunological response to the exposure to an antigen, such as a physiological or pathological condition. If the physiological or pathological condition is significant (e.g., pregnancy or cancer), the immunological response produces large numbers of specific clones which are designed to protect the body from the antigen. Applicants believe that the change in the DNA complex pattern of a healthy person after the person has been exposed to a physiological or pathological condition is most probably due to this substantial increase in the volume of white blood cell clones as compared to the volume of all other white blood cells in the blood.

JUN. 4. 2002 11:39AM

FOLEY LARDNER

NO. 3873 P. 3/3

Atty. Dkt. No. 034621-0102

9. I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

10. I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

11. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of first inventor

Gin Wu

Citizenship

U.S.A.

Post Office Address

3972 Claitor Way
San Jose, California 95132

Inventor's signature



Date

6/30/2002